DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 23, 27-30, 32, 36-40, and 42-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In **claim 23**, *line 6*, and **claim 32**, *line 5*, it is unclear as to what is meant by "of greater than about 50% to about 80%". Does "greater than about 50% to about 80%" encompass "about 50%"? It is unclear as to what the scope of the ranged encompasses. The same issued is raised with respect to **claim 42**, *line 2*, and **claim 46**, *line 2*, where it is unclear as to the range that is encompassed by the limitation "greater than about 50% to about 60%". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 23, 27-30, 32, 36, 37, 39, 42, 44-46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884) and Stinson (5,980,564).

Regarding **claim 23, 27-30, 44, 45**, Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent). The tube is formed from metal which is sintered and thereby provided as porous thereby having regions of differing porosity. The stent is cut from the tube after the tube has been formed from sintered metal. A treatment agent (i.e. therapeutic drugs) is disposed on the stent. Note that since the treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Yan discloses a stent (12) having been formed according to one embodiment, it is clearly apparent that since Yan discloses forming a stent from a porous tube via laser, it is there safe to surmise that the stent (12) in figure 1 has been formed in the same manner (i.e. laser cutting), wherein stent (12) includes a plurality of serpentine segments extending about the circumference of the stent. As a result of this laser cutting, a plurality of elongate openings are formed whose widths exceed their lengths. *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Regarding **claims 32, 36, 37, 39**, Yan discloses manufacturing a stent, wherein a tube of sintered metal is provided having different predetermined porosities. The tube is cut using a laser thereby forming a plurality of openings in the tube which in turn creates a stent (12) as previously rationalized above having multiple serpentine bands. A treatment agent (i.e. therapeutic agent) is disposed on the stent. Note that since the

treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The openings which are bounded by at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments. The first and second serpentine segments have different physical characteristics (i.e. different porosity). *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Yan, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent to one another, wherein the at least two regions having porosities of greater than about 50% to about 80% of the volume of the sintered metal; a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity; the at least two regions have porosities of greater than about 50% to about 60% of the volume of the sintered metal; or forming multiple serpentine bands such that a first band has a different porosity than a second band.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent one another, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. Solovay allows the proper amount of therapeutic agents to be delivered to the treatment site. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Stinson discloses the porosity of a region of a stent being from about 10% to about 50% of the volume of the stent which is encompassed within the range of "greater than about 50% to about 80%" based on the rationale that a percentage volume of 51% can be considered to be approximately equal to about 50% and also greater than about 50%. The porosity volume percentage of about 50% as taught by Stinson also falls within the range of greater than about 50% to about 60% as well. *See column 7, lines 62-64 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different

from the first porosity and to provide the tube of Yan with regions having porosities between greater than about 50% to about 80% of the volume of the of stent, more specifically between greater than about 50% to about 60% of the volume of the stent, in light of the respective teachings of Solovay and Stinson, in order to effectively deliver the desired amounts of therapeutic agents to a particular treatment site within the human body and to provide an effective bioabsorbable stent.

5. Claims 38, 40, 43, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan/Solovay/Stinson as applied to claims 23, 32, and 47 above, and further in view of Richter (5,807,404).

Yan/Solovay/Stinson as modified above discloses all of the claimed subject matter except for the following: a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal; the first and second side walls being non-parallel to the longitudinal axis of the stent; or at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8`,9`) of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8',9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about

the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. *See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan/Solovay/Stinson with a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal such that the first and second side walls are non-parallel to the longitudinal axis of the stent; and to provide at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal, in light of the teachings of Richter, in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted.

6. Claims 23, 27-30, 32, 36, 37, 39, 42, 44-46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884) and Cacciola (EP 040282 A1).

Regarding **claim 23, 27-30, 44, 45**, Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent). The tube is formed from metal which is sintered and thereby provided as porous thereby having regions of differing porosity. The stent is cut from the tube after the tube has been formed from sintered metal. A treatment agent (i.e. therapeutic drugs) is disposed on the stent. Note that since the treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Yan discloses a stent (12) having been formed according to one embodiment, it is clearly apparent that since Yan discloses forming a stent from a porous tube via laser, it is there safe to surmise that the stent (12) in figure 1 has been formed in the same manner (i.e. laser cutting), wherein stent (12) includes a plurality of serpentine segments extending about the circumference of the stent. As a result of this laser cutting, a plurality of elongate openings are formed whose widths exceed their lengths. *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Regarding **claims 32, 36, 37, 39**, Yan discloses manufacturing a stent, wherein a tube of sintered metal is provided having different predetermined porosities. The tube is cut using a laser thereby forming a plurality of openings in the tube which in turn creates a stent (12) as previously rationalized above having multiple serpentine bands. A treatment agent (i.e. therapeutic agent) is disposed on the stent. Note that since the

treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The openings which are bounded by at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments. The first and second serpentine segments have different physical characteristics (i.e. different porosity). *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Yan, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent to one another, wherein the at least two regions having porosities of greater than about 50% to about 80% of the volume of the sintered metal; a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity; the at least two regions have porosities of greater than about 50% to about 60% of the volume of the sintered metal; or forming multiple serpentine bands such that a first band has a different porosity than a second band.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent one another, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. Solovay allows the proper amount of therapeutic agents to be delivered to the treatment site. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Cacciola discloses the porosity a microporous support tube having a porosity of from about 5% to about 60% of the volume of the sintered metal which overlaps the range of greater than about 50% to about 80%, in order to support particles used to form the membrane coating. *See page 8, lines 10-19 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity and to provide the tube of Yan with regions having porosities between greater than about 50% to about 80% of the volume of the of stent, more

specifically between greater than about 50% to about 60% of the volume of the stent, in light of the respective teachings of Solovay and Cacciola, in order to effectively deliver the desired amounts of therapeutic agents to a particular treatment site within the human body and to in order to support particles used to form the membrane coating.

7. Claims 38, 40, 43, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan/Solovay/Cacciola as applied to claims 23, 32, and 47 above, and further in view of Richter (5,807,404).

Yan/Solovay/Cacciola as modified above discloses all of the claimed subject matter except for the following: a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal; the first and second side walls being non-parallel to the longitudinal axis of the stent; or at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8`,9`) of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8',9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine

segment. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. *See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan/Solovay/Cacciola with a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal such that the first and second side walls are non-parallel to the longitudinal axis of the stent; and to provide at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal, in light of the teachings of Richter, in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted.

Response to Arguments

8. Applicant's arguments filed 1/25/08 have been fully considered but they are not persuasive.

Applicant argues that since the Oath/Declaration was not declared defective when the first Office Action was mailed on January 29, 2002 and that according to the MPEP the Office is estopped from asserting that the declaration is defective.

In response, the Examiner has withdrawn the objections to the oath/declaration.

Applicant argues with the combination of references, that secondary reference to Stinson and the combination itself fails to regions having porosities of greater than about 50% to about 80%.

In response, the Examiner maintains that the limitation "of greater than about 50% to about 80% is encompassed the teaching of Stinson at col. 7, lines 62-64 where Stinson teaches the porosity being up to about 50%, wherein hypothetically 51% can be can be considered to be about 50% and it can also be considered to be greater than about 50%. It is unclear from the claims as iterated in the 112, 2nd paragraph above as to the scope or boundary of the range presented therein. Therefore based on the rationale just provided, the teachings of Stinson meet the lower end range of the claim and therefore the combination of references render the claimed invention obvious. Applicant is directed to explicitly clarify the scope of the range in order to avoid any ambiguity and indefiniteness as it relates to the claimed invention.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie E. Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jermie E Cozart/
Primary Examiner, Art Unit 3726

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